## IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Application of: McGee et al. Confirmation No.: 1490

Serial No.: 10/719,997 Art Unit: 1625

Filed: November 20, 2003 Examiner: Seaman, D. Margaret

For: Quinolinyl and Benzothiazolyl Attorney Docket No.: 11134-096-999

Modulators

## DECLARATION OF LAWRENCE R. MCGEE UNDER 37 C.F.R. § 1.131

Commissioner for Patents P.O. Box 1450 Alexandria, VA 22313-1450

I Lawrence R. McGee, Ph.D., residing at 39 Big Sur Way, Pacifica, CA 94044, hereby declare that:

- 1. I am a co-inventor of the presently claimed invention in the above-identified U.S. patent application.
- 2. I received a Ph.D. degree in Chemistry from the California Institute of Technology in 1982.
- 3. I currently hold the position of Scientific Director, Amgen SF Medicinal Chemistry at Amgen Inc., 1120 Veterans Blvd., South San Francisco, CA 94080.
- 4. I have reviewed the specification of the above-identified patent application and understand that this patent application relates to quinolinyl modulators of the peroxisome proliferator-activated receptor gamma ("PPARγ). I have further reviewed the currently-pending claims and understand that the currently claimed invention encompasses compounds of Formula I, as set forth below, and compositions comprising the compounds.

Formula I

wherein

A is Cl or CF<sub>3</sub>;

C is Cl or CF<sub>3</sub>;

D is H or CH<sub>3</sub>;

V is F or Cl;

X is a member selected from the group consisting of H, CH<sub>3</sub>, COOH, and CO<sub>2</sub>CH<sub>3</sub>; and

Y is a member selected from the group consisting of H, CO<sub>2</sub>H and CO<sub>2</sub>CH<sub>3</sub>;

or a pharmaceutically acceptable salt thereof.

5. I and my co-inventors synthesized a number of compounds encompassed by the formula set forth above prior to May 3, 2000. These compounds are documented, at least in part, in my laboratory notebook and in the laboratory notebook of individuals working at my direction. These notebooks show the structure of the compounds and the date such compounds were synthesized or communicated to me by my co-inventors. A copy of notebook 1758, page 18 is attached hereto as Exhibit A. A copy of notebook 1758, page 28 is attached hereto as Exhibit B. A copy of notebook 1758. page 43 is attached hereto as Exhibit C. A copy of notebook 1758, page 48 is

attached hereto as Exhibit D. A copy of notebook 1736, page 89 is attached hereto as Exhibit E. A copy of notebook 1736, page 91 is attached hereto as Exhibit F. A copy of notebook 1758, page 79 is attached hereto as Exhibit G.

- Prior to May 3, 2000, in the United States, I and my co-inventor Dr. Steven M.
   Rubenstein synthesized or directed the synthesis of compounds according to Formula
   I, wherein
  - A is CF<sub>3</sub>, C is Cl, D is H, V is Cl, and X and Y are each H (See Exhibit E);
  - A is Cl, C is CF<sub>3</sub>, D is H, V is Cl, and X and Y are each H (See Exhibit F).
- 7. Prior to May 3, 2000 and after January 1, 1996, in Japan, one or more of my coinventors Atsushi Hagiwara, Noboru Furukawa, and/or Hisashi Shinkai synthesized, or directed the synthesis of, compounds according to Formula I, wherein
  - A is Cl, C is Cl, D is H, V is Cl, and X and Y are each H (See Exhibit A);
  - A is Cl, C is Cl, D is CH<sub>3</sub>, V is Cl, and X and Y are each H (See Exhibit B);
  - A is Cl, C is Cl, D is H, V is Cl, X is CO<sub>2</sub>CH<sub>3</sub>, and Y is H (See Exhibit C);
  - A is Cl, C is Cl, D is H, V is Cl, X is H, and Y is CO<sub>2</sub>CH<sub>3</sub> (See Exhibit C);
  - A is Cl, C is Cl, D is H, V is Cl, X is CO<sub>2</sub>H, and Y is H (See Exhibit C);
  - A is Cl, C is Cl, D is H, V is Cl, X is H, and Y is CO<sub>2</sub>H (See Exhibit C);
  - A is Cl, C is Cl, D is CH<sub>3</sub>, V is Cl, X is CH<sub>3</sub>, and Y is H (See Exhibit D); and
  - A is Cl, C is Cl, D is CH<sub>3</sub>, V is F, and X and Y are each H (See Exhibit G).

The structures of these compounds and a sample of each compound were communicated to me prior to May 3, 2000, as shown in the respective Exhibits identified above.

8. Although the dates of the laboratory notebook pages, the compound numbers, and unrelated compounds have been redacted to preserve confidentiality, I have reviewed each page or was involved in the project such that I can attest that the date of each of the laboratory pages was prior to May 3, 2000.

9. I declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of United States Code and that such willful false statements may jeopardize the validity of the application of any patent issuing thereon.

Date: 22 Jan 2004 Z 1 Mrsec

Lawrence R. McGee